

considerably more flexible than the main wire body 182 and, in turn, the leaf 194 is even more flexible and particularly along the axis 196. The distal portion 184 of the device includes a wire coil 202 wound around the distal portion 184 and affixed by means of a proximal weld 204 at the tapered transition 190 and a distal weld 206 at the leaf tip 198. The wire coil 202 preferably has an outer diameter equal to that of the main wire body 182. By way of example and not limitation, the wire coil 202 may be made of wire having a gauge of about 39 Brown and Sharpe wound with a pitch of about 280 turns per inch. Further, by way of example and not limitation, the leaf 194 may have a thickness from about .001 to about .005 inch and a length of about 0.5 to about 5.0cm. The length of the proximal section 186 may range from about 3 to about 30cm in which case the overall length of the distal portion 184 may range from about 3.5 to about 35 cm. Again, these dimensions are exemplary only; suitable dimensions for a specific case will be evident to those skilled in the art.

FIG. 11 shows the distal part of a device 210 in accordance with a sixth embodiment of the invention. The device 210 includes a main wire body 212 and a flexible distal portion 214 that, in accordance with a preferred form of the sixth embodiment, comprises a stepped cylindrical structure including a flexible proximal section 216 and an even more flexible distal section 218. The proximal section 216 has a diameter smaller than that of the main wire body 212 and the distal section 218 has a diameter smaller than that of the proximal section 216. The main wire body 212 and the sections 216 and 218 may be fabricated as a one-piece or unitary structure, or may be formed separately and welded or otherwise bonded together. As in the embodiment of FIGS. 8-10, the distal portion 214 may be enveloped within a wire coil welded or otherwise bonded at its proximal and distal ends to the distal portion 214.

Each of the devices 60, 90, 120, 150, 180 and 210 may be coated with PTFE to make it lubricious to facilitate passage through the lumen of the associated lead. A further enhancement may be to coat the device

with heparin to inhibit coagulation of the blood on the surface of the device.

With reference now to FIGS. 12-15, and taking the device 60 as exemplary of the various embodiments of the invention, the steps in using the device of the invention to direct and place a lead body 12 within the coronary sinus region 79 of the heart will now be described. The device 60 is first inserted in the lead body 12 with the flexible distal portion 70 in a retracted position within the distal portion 14 of the lead (FIG. 12). An introducer sheath 80 is then inserted through the superior (SVC) 82 as is well known in the art. The introducer 80 may be long enough to reach the coronary OS 84 and may be precurved to facilitate the directing of the lead. The lead body is inserted into the introducer 80 and advanced therein. (FIG. 13). The device 60 of the invention is then advanced relative to the lead body to extend the flexible distal portion 70 of the device and expose it distally of the tip electrode 18 which defines a central aperture through which the portion 70 passes. (FIG. 14.) By manipulating the steering knob 68 on the proximal extremity 64 of the main wire body 62, the device 60 is maneuvered into position within the coronary sinus region 79 and specifically into the left posterior ventricular (LPV) vein 86 in this particular case. Next, the lead body is moved into place "over-the-wire", that is, it is slid along the device 60 into place within the target coronary vessel. (FIG. 15). Last, the device 60 and the introducer sheath 80 are withdrawn.

It will be seen that unlike the prior art, the lead body 12 provides the guide or delivery tool for the flexible distal portion of the device of the invention. It will also be appreciated that the device of the present invention has the advantage of greatly speeding up the process of lead implantation. It avoids both the relative inflexibility of a stylet and the awkwardness of using an unduly long guide wire yet it is designed for use with a lead body designed for over-the-wire placement with all of the attendant advantages.

While several illustrative embodiments of the invention have been shown and described, numerous variations and alternate embodiments will occur to those skilled in the art. Such variations and alternate embodiments are contemplated, and can be made without departing from the spirit and scope of the invention as defined in the appended claims.

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